

## **REMARKS**

A "Non-responsive amendment" canceling claim 12 was filed electronically with a one month extension of time on July 23, 2007, the same day this response was filed by regular mail. Therefore, no further extension fees are required to consider this response. The non-responsive amendment was filed to eliminate an obviousness type double patenting rejection in copending US Application No. 09/889,227.

### **Election /Restriction Requirement**

Each of the pending claims reads on the elected subject matter following the amendments above. Claims 2, 5, 6, 12, 40-42, 44 and 50-53 have been canceled. Claim 39 has been amended to depend on claim 4 and now incorporates the elected disease state (arthritis) and the elected compound, *N*-(4-chloro-3-(trifluoromethyl)phenyl)-*N'*-(4-(2-(*N*-methylcarbamoyl)-4-pyridyloxy)phenyl) urea. Claim 43, which depends on claim 39 and specifically recites the elected compound, now also reads on the elected subject matter. Claim 49, which depends on claim 43, also reads on the elected subject matter.

Claims 45-48 have been amended to depend on claims 1, 4, 10 and 11, claims which have been found to read on the elected subject matter. Claims 45-48 now also define subject matter with in the elected group.

### **Double Patenting Rejection /Copending Applications**

Applicants traverse the obviousness type double patenting rejections based on the following applications:

09/889,227  
10/071,248  
09/948,915  
10/361,858  
09/993647  
10/042,203  
10/361,859  
10/308,187 and  
10/895.985.

1) Copending US application No. 09/889,227 no longer contains any method

of treatment claims such that the methods claimed herein are patentably distinct from the subject matter claimed in US application No. 09/889,227.

2) Copending application US 10/071,248, contains claims directed to specific ureas and their use in treating osteoporosis and inflammation. The compounds claimed and used in these methods are patentably distinct from those used in methods claimed herein. The urea compounds claimed in copending application US 10/071,248 require at least one "OH" substituent or a "-OC(O)C<sub>1</sub>-C<sub>4</sub> alkyl" substituent. The compounds employed in the methods claimed herein are not restricted to such compounds. No evidence has been presented that one skilled in the art would be motivated to select the compounds of copending application US 10/071,248 from those used in the methods claimed herein and no reason has been given why one skilled in the art would eliminate a required substituent of the compounds claimed in US 10/071,248 to arrive at the compounds used in the methods of this invention. Therefore, applicants submit the subject matter of the claims in copending US Application No. 10/071,248 does not render the claims herein obvious such that the obviousness type double patenting rejection based on US Application No. 10/071,248 should be withdrawn.

3) Copending application US 09/948,915, does not contain any method claims directed to the treatment of inflammatory diseases such as arthritis. The compositions claimed in copending application US 09/948,915 are said to be suitable for treating cancer and tumors. The methods which have been claimed are (or were) directed to treating cancers and tumors mediated by raf kinase. One skilled in the art would not find the treatment methods claimed obvious in view of the subject matter claimed in copending application US 09/948,915, such that the obviousness type double patenting rejection based on the 09/948,915 application should be withdrawn.

4) Copending US Application 10/361,858, was filed subsequent (effective filing date = February 11, 2002) to the application herein (effective filing date = January 13, 1999). If this provisional obviousness type double patenting rejection is the only outstanding rejection of the claims herein, MPEP 804 (I)(B), provides guidance on how to address obviousness-type double patenting issues. Relevant portions of MPEP 804 (I)(B) read as follows:

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.

#### >Nonstatutory Double Patenting Rejections

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the other later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should then withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without the need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

In view of MPEP 804 (I)(B), withdrawal of the obviousness type double patenting rejection based on copending US Application 10/361,858 is appropriate since no other rejections of the pending claims has been identified.

4) Copending application US 09/993,647, is directed to methods for treating cancers such as solid tumors, carcinomas and myeloid disorders, adenomas and diseases mediated by raf. These methods are patentably distinct from the methods claimed herein for treating p38 mediated diseases/inflammatory diseases and arthritis. One skilled in the art could not predict the activity required of the methods claimed

herein based on the anti-cancer treatment methods of copending application US 09/993,647, such that there is no basis for rejecting the pending claims under the doctrine of obviousness type double patenting.

6) Copending application US 10/042,203, issued as US patent 7,235,576 B1 with incorrect claims. A certificate of correction has been filed to correct the patent, which should have issued with only claims to pharmaceutically acceptable salts and pharmaceutical compositions obtained therefrom. There is no basis for finding the claims herein obvious in view of the allowed claims in Copending application US 10/042,203.

7) Copending application US 10/361,859, has claims directed to compounds (N-oxides) which are patentably distinct from the compounds employed in the methods of this invention. These n-oxides are not encompassed by the broad generic disclosure of compounds employed in the methods of claim 1 herein. Therefore, these claims are not obvious in view of the claimed subject matter (n-oxides) of US Application No. 10/361,859.

8) Copending application US 10/308,187, defines methods for treating cancer with combinations of drugs. These methods shed no light on the use of the compounds recited in claim 1 herein and others in treating p38 mediated diseases such as inflammation/arthritis.

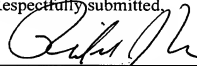
9) Copending application US 10/895,985 contains claims to a specific compound which is patentably distinct from the compounds defined in the methods claimed herein such that the obviousness type double patenting rejection should be withdrawn. In addition The subject application was filed before copending application 10/895,985 as well as 10/361,859 and 10/308,187 and is therefore, the "earlier filed application" under MPEP 804 (I)(B) with respect to each of these applications. Based on the procedures set forth in MPEP 804 (I)(B), the nonstatutory "provisional" obviousness-type double patenting rejections based on these applications should be withdrawn without filing a terminal disclaimer in the subject

application.

In view of the above remarks, applicants submit that the claims herein should be allowed without a filing terminal disclaimer for any of the copending applications cited. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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